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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,206	07/20/2006	Akikuni Yagita	20080-00004	7734

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JHK LAW
P.O. BOX 1078
LA CANADA, CA 91012-1078

EXAMINER

NATARAJAN, MEERA

ART UNIT	PAPER NUMBER
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1643

MAIL DATE	DELIVERY MODE
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11/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/597,206	Applicant(s) YAGITA, AKIKUNI	
	Examiner Meera Natarajan	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-8 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-8 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group III, claims 6-8 and 15 in the reply filed on 10/22/2007 is acknowledged.
2. Claims 1-5 and 9-14 have been canceled by Applicant without prejudice.
3. Claims 6-8 and 15 will be examined on the merits.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 6-8 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yagita et al. (PgPub: 20020064522, published 05/2002) in view of Tsukagoshi et al. (Cancer and Chemotherapy Vol. 28(10), pp.1461-1467, 2001).

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7. The claims are drawn to a method to treat pancreas or bile duct cancer comprising administering to a patient Gemcitabine Hydrochloride and an IL-12 production-inducing agent, wherein said patient is producing less than 7.8 pg/ml IL-12.

8. Yagita et al. teach a composition comprising activated hemicellulose (AHCC) which induces IL-12 production in vivo, and a method for treating cancer by administering said composition to a patient. Yagita et al. also disclose a method of combined administration of AHCC (IL-12 inducing agent) and PSK (an anti-cancer agent – see section [0013]) (see examples 7 and 8). The additional PSK administration was effective to promote anti-cancer effect of AHCC in lung, hepatic, stomach, large intestine, pancreatic and kidney cancer (see section [0057]). Yagita et al. also disclose AHCC caused serum IL-12 levels to increase as high as 78 pg/ml and states that a normal value is lower than 7.2 pg/ml. Yagita et al. does not teach the administration of Gemcitabine Hydrochloride. This deficiency is made up for by Tsukagoshi et al.

9. Tsukagoshi et al. teach gemcitabine hydrochloride in the treatment for pancreatic cancer. It is well known in the art that gemcitabine hydrochloride is an anti-cancer agent. Tsukagoshi et al. teach clinical efficacy of gemcitabine hydrochloride as a novel anti-tumor agent for pancreatic cancer (see Abstract). Tsukagoshi et al. suggest the treatment of pancreatic cancer with gemcitabine hydrochloride in combination therapy with other anti-cancer drugs (see Abstract).

10. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute the anti-cancer agent,

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PSK, for gemcitabine hydrochloride in combination with the IL-12 inducing agent taught by Yagita et al. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in Yagita et al. and Tsukagoshi et al. because Tsukagoshi et al. teach gemcitabine hydrochloride is a successful anti-cancer treatment for pancreatic cancer.

Conclusion

11. Claims 6-8 and 15 are rejected.
12. No claim is allowed.
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meera Natarajan whose telephone number is 571-270-3058. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

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system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service

Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN



LARRY R. HELMS PH.D.
SUPERVISORY PATENT EXAMINER